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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,184	07/11/2003	David Frederick Horrobin	P63461US4	3007

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EXAMINER
WILLIAMS, LEONARD M

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,184	HORROBIN, DAVID FREDERICK	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) *4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

VB

Detailed Action

Priority

This application is a division of Application No. 09/956739 (now US Patent No. 6624195), filed 09/18/2001, which was a division of Application No. 09/284231 (now US Patent No. 6351568) filed on 06/10/1999.

Claim Objections

Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not be drawn to another multiple dependant claim. Claim 4 states: "A pharmaceutical preparation according to claim 1 or 3 or method according to claim 2 or 3 but for the treatment of depression". Claim 5 states: "A pharmaceutical preparation according to claim 1 or 3 or method according to claim 2 or 3 but for the treatment of Alzheimer's disease or other dementias", See MPEP § 608.01(n).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6 and 7 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5120760. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are drawn to pharmaceutical preparation, methods of treating, and methods of preparation of compositions useful in the treatment of schizophrenia and/or tardive dyskinesia by administering an oil comprising n-3 fatty acids such as eicosapentaenoic acid (EPA) and/or stearidonic acid (SA) in varying amounts with or without the presence of n-6 fatty acids such as gamma-linolenic acid.

US Patent No. 5120760 is drawn to a method of treating tardive dyskinesia comprising administering a composition comprising GLA and higher n-6 series acids, with SA and higher n-3 series fatty acids in effective daily amounts of 10mg and 50g of each acid.

The present application and patent are commensurate in scope, target the same disorder, and share the same inventor, but do not have the same assignee. An obviousness type double patenting rejection is appropriate.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states "...in amounts of more than 20%, preferably more than 40% and very preferably more than 70%..." The term "preferably" makes the claim indefinite as it is not clear what amount is claimed. Correction is required.

Claim 2 states "A method of treating, or a method of preparation of a medicament for treating..." these are two different statutory classes of invention (a method of treating and a method of making) and make the present claim unclear as to which invention the applicants are drawing the claim to. Additionally claim 2 states "...in amounts of more than 20%, preferably more than 40% and very preferably more than 70%..." The term "preferably" makes the claim indefinite as not specifying as to amount is claimed. Correction is required.

Claim 3 states: "A pharmaceutical preparation according to claim 1, or a method according to claim 2..." Claim 2 as shown above is drawn to two statutory classes of invention involving methods. It is not clear if the "method according to claim 2" is referring to the method of treating or the method of preparation of a medicament. Correction is required.

Claim 6 states: "Pharmaceutical preparation or medicament prepared as above which is suited to, or a method of treatment as above..." The claim is not clear or distinct as to what the applicant is claiming. The pharmaceutical preparation or

medicament is a composition, the method of treatment is a method. They are two separate statutory classes of inventions. The phrase "...as above..." is indefinite as it does not specify which claim is referred to. The term "...suited to..." is indefinite as it is not clear what the term means in the context of the claim.

The examiner respectfully points out the following from section 608.01(m) [R-2] Form of Claims of the MPEP:

> The claim or claims must commence on a separate *>physical sheet or electronic page<and should appear after the detailed description of the invention. >Any sheet including a claim or portion of a claim may not contain any other parts of the application or other material.< While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim," "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the **>Office of Patent Publication<. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).
>
> Claims should preferably be arranged in order of scope so that the first claim presented is the least restrictive. All dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable. Where separate species are claimed, the claims of like species should be grouped together where possible. Similarly, product and process claims should be separately grouped. Such arrangements are for the purpose of facilitating classification and examination.

Claim 7 provides for the use of "EPA and/or SA in the preparation of a medicament for the treatment of schizophrenia...", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin (US Patent 5120760).

Horrobin teaches, in col. 4 lines 25-37 and claims 1 and 2, methods and preparations of medicaments for treating schizophrenia and/or associated tardive dyskinesia by combining an n-6 EFA (GLA, DGLA, or AA) with an n-3 EFA (stearidinic acid, EPA, 22:5 n-3 or DHA).

Claims 1 and 2 of the Horrobin patent are stated below (US Patent 5120760):

1. A method of treating tardive dyskinesia comprising administering to a patient in need of same an effective amount of a composition comprising an essential fatty acid selected from GLA and higher n-6 series acids with an essential fatty acid selected from stearidonic acid and higher n-3 series acids in effective daily amounts of 10mg and 50g of each acid.

2. The method according to claim 1, wherein the n-6 EFA is selected from GLA, DGLA, and AA and the n-3 EFA is selected from stearidonic acid, EPA 22:5 n-3 and DHA.

Based on the limitations detailed in claims 1 and 2 of the patent above one could prepare a composition that comprised 7g of EPA, 2g of stearidonic acid, and 1g of GLA for a total composition weighing 10g anticipating "a pharmaceutical preparation...using an oil comprising EPA and/or stearidonic acid..." of claim 1. The EPA would comprise 70% of the composition, the steardonic acid would comprise 20% of the composition, and the GLA would comprise 10% by weight of the total composition. The total percentage by weight of the n-3 EFAs would be 90% anticipating the "...more than 20%, preferably more than 40%, and very preferably more than 70% by weight..." EPA/SA to total fatty acids present, additionally the n-3 to n-6 ratio of the forementioned composition would be 9:1 anticipating the "...wherein the weight ratio of SA/EPA to n-6 EFAs present is not less than 3:1 and is preferably 4:1 or more..." of claim 1 and the "...method of treating, or a method of preparation of a medicament for treating..." of claim 2. As there is no requirement in the applicants claims that DHA be present at all the "...pharmaceutical preparation...or method according...wherein the weight ratio of SA/EPA to any DHA is not less than 3:1 and is preferably 4:1 or more" is anticipated by the composition set forth above. The limitations set forth in claims 1 and 2 of the Horrobin patent as stated above anticipate the "...pharmaceutical preparation or medicament..." of claim 6 and the "use of EPA and/or SA in the preparation of a medicament..." of claim 7.

Claim 4 is drawn to "A pharmaceutical preparation...but for the treatment of depression". Claim 5 is drawn to "A pharmaceutical preparation...but for the treatment of Alzheimer's disease or other dementias". The examiner respectfully points out that

the phrase "...for the treatment of..." is part of the preamble to a composition claim and that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Claims 4 and 5 are rejected for reasons as set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

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